

IMPORTANT MESSAGE TO: All Lions, corneal surgeons and patients served by the free services of the Florida Lions Eye Bank.

RE: FDA Proposed Rule: Suitability Determination for Donors of Human Cellular And Tissue Based Products

Cite: 21 CFR Parts 210, 216, 820 and 1271 (Docket No. 97N-4845)

WebSite Access: (FDA)WWW.FDA.GOV/CBER/RULES/SUITDONOR.PDF

On 10/30/99 the FDA published a proposed rule to require screening and testing for risk factors for and clinical evidence of relevant communicable disease agents and diseases.

We are alerting each of you to this proposed regulation which threatens to reduce the number of surgical quality corneas this and many other large eye banks will be able to provide in the near future. The FDA Rule requires a donor medical history interview, even when the donor is a medical examiner case.

During 1998 the Florida Lions Eye Bank obtained at the Dade, and Broward County Medical Examiner's Office approximately 900 surgical quality corneas under Florida Statute 732.99185 (a law which has been in effect in this state since July 1977). We then processed, screened and provided these corneas totally free of charge for transplant surgery. The required additional screening would require, in our opinion, an unnecessary and time consuming step in the process of obtaining corneas and would greatly hamper our efforts to serve Floridians in need of sight restoring corneal transplant surgery. If the additional screening could insure that corneal tissue did NOT come from a donor having a communicable disease...we would agree that the additional step was necessary. However, many extremely credible medical advisors do not believe that the proposed required screening which involves locating the donor's next of kin to ask certain questions would result in the additional safety of the corneas.

The Florida Lions Eye Bank has operated efficiently and effectively since the passage of FI Statute 732.99185, mostly due to co-operation of South Florida Medical Examiners. Proof of this is the fact that between July 1977 and July 1999 this eye bank retrieved, screened and provided more than 28,000 totally free corneas, most of which obtained with the use of the statute. During that time there has never been any evidence of transmission of Creutzfeldt Jakob Disease (CJD) to a recipient by any one of those corneas. We agree with the opinion of Doctor Joseph H. Davis, Director Retired of Miami-Dade County Medical Examiner Department that the "ME donor pool has better quality control standards than the hospitalized chronically ill elderly pool". Until there is a proven blood test to detect CJD, the FDA cannot insure that any donor does not harbor that disease simply by requiring a donor medical history interview.

You can help by writing to the FDA to express your concern over how this proposed rule will affect the supply of surgical corneas in South Florida. Letters must arrive prior to December 16, 1999 and should be mailed to:

**The Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852**

97N-4845

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December 3, 1999

The Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: 21 CFR Parts 210, 211, 820, and 1271
Suitability Determination for Donors of Cellular & Tissue-Based Products

To Whom It May Concern:

As a member of one of the 150 Lions Clubs in South Florida consisting of more than 6,000 men and women, I am writing to express my opposition to the proposed Food and Drug Administration's rule to require a donor medical history interview for all corneal donors. I am proud of the fact that the Florida Lions Eye Bank has, over the past 38 years, provided more than 32,000 corneas to patients totally free of charge. This has saved the Medicare program more than \$1,000,000 each year from our eye bank alone.

The FDA's effort to address transmission of Creutzfeldt Jakob Disease (CJD) will eliminate the most successful eye bank program in the nation. While the motive is admirable, the new requirement will not serve that purpose. Our medical advisors state that the additional next of kin screening requirements will not add to the safety of corneal tissue for CJD. This has been well demonstrated 32,000 times over the past 38 years.

As you must know, patients who have the symptoms for CJD usually die in hospitals and are of advanced age (over 60). The Florida Lions Eye Bank's Medical Examiner's program obtains corneas from those who dies in a sudden accidental death. Their ages typically range from 20-40 years of age. This is not a high risk group. Also, those who die a sudden death from other causes, but who might have the disease in the latent stage, would not exhibit any symptoms of CJD...thus asking even hundreds of questions regarding behavior, etc. would serve no purpose.

Each day here in South Florida many new patients are added to the waiting list for corneal transplantation. Unnecessary screening will further delay the wait time and extend the suffering and impaired vision of many men, women, and children. In addition, if the eye bank is forced to hire more employees to try to track down someone to interview on each suitable case at the, medical examiner's offices, it will become necessary to begin to charge a processing fee. Since the majority of corneal recipients are over 65, the government will be charged for a service provided free for 38 years.

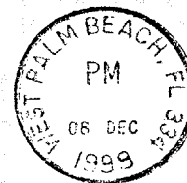
Sincerely,

cc: Senators: Bob Graham, Connie Mack

Representatives Dan Miller, Dave Weldon, Carrie Meek, Ileana Ros-Lehtinen, Robert Wexler, Joe Scarborough, E. Clay Shaw, Jr., Alcee Hastings, Tille Fowler, Karen Thurman, Cliff Stearns, John Mica, Bill McCollum

Raymond J. Fox Deerfield Lions
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